

## The Office Action

The Office Action made the following rejections/objections:

- (1) the disclosure has been objected to for certain informalities;
- (2) claims 1-20 have been rejected under 35 U.S.C. Sec. 112, first paragraph, for lack of enablement;
- (3) claims 1-20 have been rejected under 35 U.S.C. Sec. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention;
- (4) claims 1-20 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of co-pending U.S. Patent Application Serial No. 09/216,448;
- (5) claims 1-20 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of co-pending U.S. Patent Application Serial No. 09/216,247;
- (6) claims 1-19 have been rejected under 35 U.S.C. Sec. 102(b) as being anticipated by *Lacy et al.*, U.S. Patent No. 5,645,856; and,
- (7) claims 1-20 have been rejected under 35 U.S.C. Sec. 103(a) as being unpatentable over *Lacy et al.*, U.S. Patent No. 5,645,856.

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Modifications of Claims Unrelated to Prior Art Rejections

The modifications of claims 4, 7, 15-17 and 20, and the cancellation of claims 9-11 and 18 made by this amendment are unrelated to prior art rejections, but rather have been made to clarify the claims. These amendments therefore add no new matter to the specification; and entry into the record is respectfully requested.

Discussion of the Objection to the Disclosure

The disclosure is objected to for certain informalities. Specifically, the Office Action stated that Figures 1 and 2 should be canceled from the specification and submitted as separate sheets. Accordingly, by this Preliminary Amendment, Applicants have requested cancellation of the Figures from pages 6 and 7, and submitted them separately as Formal Drawings which accompany this amendment. Therefore, Applicants respectfully submit that this objection has been overcome.

Discussion of the 35 U.S.C. Sec. 112, First Paragraph Rejection

Claims 1-20 have been rejected under 35 U.S.C. Sec. 112, first paragraph, for lack of enablement. Specifically the Office Action stated that the specification enables fenofibrate, but does not provide for the generic “lipid-regulating agent” and “structured lipid” specified in claim 1.

Applicants have disclosed compositions of and processes for making formulations containing lipid-regulating agents. Specific examples of lipid-regulating agents are fibrates such U.S.S.N. 09/216,242

as fenofibrate. Applicants submit that the specification enables the invention as set forth in claim 1. 35 U.S.C. Sec. 112, in relevant part provides that “[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.” This requires an applicant to provide sufficient information so that one of ordinary skill in the art can practice the claimed invention without the necessity for undue experimentation.

The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art... The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed... In re Wands, 8 U.S.P.Q.2d, 1400, 1404 (Fed. Cir. 1988).

The invention is directed to compositions of lipid-regulating agents with enhanced dissolution and absorption characteristics. The specification describes methods for preparing the formulations on page 4, line 21 to line 32. The specification further contains examples in which formulations of a lipid-regulating agent were prepared.

On the basis of Applicants's disclosure, one of ordinary skill in the art would be able to prepare formulations including other lipid-regulating agents as recited in claim 1. As claims 2-8, 12-17, 19 and 20 depend upon claim 1, Applicants believe that these more specific claims are also adequately enabled. Applicants therefore submit that the specification fully enables the claimed invention.

Applicants also respectfully submit that a requirement to limit the claims to fibrates would be contrary to public policy as set forth in In re Goffe, 191 U.S.P.Q. 429, 431 (C.C.P.A. 1976):

For all practical purposes, the board would limit appellant to claims involving the specific U.S.S.N. 09/216,242

materials disclosed in the examples, so that a competitor seeking to avoid infringing the claims would merely have to follow the disclosure in the subsequently-issued patent to find a substitute. However, to provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for preferred materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

In the present case, claims limited to compositions of fibrates would not adequately protect the inventors. Based on the teachings of the present specification, one skilled in the art would attempt to formulate other compositions containing other lipid-regulating agents and thereby attempt to circumvent the literal scope of Applicants' patent rights.

Concerning the phrase "structured lipid" of claim 1, representative structured lipids are identified on page 3, lines 34-39. On page 3, lines 37-38, the specification states that these are "lipids containing saturated medium and long chain fatty acids esterified to the same glycerol molecule." Applicants submit that the specification adequately enables this phrase.

Therefore, Applicants respectfully request withdrawal of the Sec. 112, first paragraph rejection of the claims.

Discussion of the 35 U.S.C. Sec. 112, Second Paragraph Rejection

Claims 1-20 have been rejected under 35 U.S.C. Sec. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically the Office Action stated that 1) the phrase "structured lipid" in claim 1 is unclear; 2) proper Markush format should be utilized in claims 4, 7 and 20; and 3) claim 9 is unclear in light of claim 1.

Concerning the first aspect of the rejection, Applicants submit that the phrase "structured lipid" in claim 1 is clear. As noted above, representative structured lipids are identified on page

3, lines 34-39. On page 3, lines 37-38, the specification states that these are "lipids containing saturated medium and long chain fatty acids esterified to the same glycerol molecule."

Applicants submit that this phrase is not vague.

By this Preliminary Amendment, claims 4 and 20 have been amended to reflect proper Markush format, and claim 7 has been amended to omit improper format, so Applicants submit that the second aspect of the rejection has been overcome.

By this Preliminary Amendment, claim 9 has been canceled, and therefore Applicants submit that the third aspect of this rejection has been overcome.

As claims 2-8, 12-17, 19 and 20 depend upon claim 1, Applicants submit that the more specific dependent claims are also not indefinite. Therefore, Applicants respectfully request withdrawal of the Sec. 112, second paragraph rejection.

#### Discussion of the Obviousness-Type Double Patenting Rejection

Claims 1-20 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of co-pending U.S. Patent Application Serial No. 09/216,448. Specifically, the Office Action stated that although the conflicting claims are not identical, they are not patentably distinct from one another because the "structured lipid" of the co-pending application encompass the species in the claims of the present application.

A Terminal Disclaimer over co-pending U.S. Patent Application Serial No. 09/216,448 accompanies this Preliminary Amendment. Therefore Applicants respectfully request withdrawal of the obviousness-type double patenting rejection.

#### Discussion of the Obviousness-Type Double Patenting Rejection

Claims 1-20 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of co-pending U.S. Patent Application Serial No. 09/216,247. Specifically, the Office Action stated that although the conflicting claims are not identical, they are not patentably distinct from one another because U.S.S.N. 09/216,242

the “structured lipid” of the co-pending application encompass the species in the claims of the present application.

A Terminal Disclaimer over co-pending U.S. Patent Application Serial No. 09/216,247 accompanies this Preliminary Amendment. Therefore Applicants respectfully request withdrawal of the obviousness-type double patenting rejection.

Discussion of the 35 U.S.C. Sec. 102(b) Rejection

Claims 1-19 have been rejected under 35 U.S.C. Sec. 102(b) as being anticipated by Lacy *et al.*, U.S. Patent No. 5,645,856. Specifically the Office Action stated that the cited reference discloses capsules containing emulsions of fenofibrate; wherein the emulsions contain a triglyceride, polyglycerol esters of fatty acids and a co-solvent, which further contain capric/caprylic triglycerides such as MIGLYOL and CAPTEX.

As an initial matter, Applicants note that the Examiner did not include claim 20 in this rejection. Applicants respectfully request that the Examiner confirm that claim 20 is free of the 35 U.S.C. Sec. 102(b) rejection over Lacy *et al.*

Lacy *et al.* disclose compositions of hydrophobic drugs in carriers, wherein the carrier includes a digestible oil and a surfactant. Appropriate surfactants are combinations of lipophilic surfactants and hydrophilic surfactants, as stated in col. 3, lines 50-67 of the cited reference. Preferred digestible oils include medium chain triglycerides, as disclosed in col. 8, line 55-col. 9, line 28 of the cited reference. However, these digestible oils are part of a carrier which also includes a surfactant. Note that col. 9, lines 49-54 indicate the undesirability of a medium chain triglyceride, since it undergoes rapid lipolysis. The cited reference discloses that compositions including a lipophilic surfactant reduce this undesirable tendency in col. 4, lines 6-14. Moreover, the table in col. 10, lines 20-29 illustrates that the carriers of the cited reference include digestible oil, hydrophilic surfactant and lipophilic surfactant. Therefore the cited reference teaches away from the present invention as set forth in claim 1, which does not require a lipophilic surfactant.

In addition, Applicants wish to point out to the Examiner that compositions of lipid-U.S.S.N. 09/216,242

regulating agents of the cited reference are only disclosed in a formulation as Formulation A of Example 6, which is a solution of fenofibrate in soybean oil, polysorbate 80, triacetin and priolene; or as Formulation D, which is a suspension formulation of probucol in soybean oil, priolene and polysorbate 80. No specific examples of lipid-regulating agents in structured lipids are presented in the cited reference.

By contrast, Applicants' invention, as set forth in claim 1 is a composition of a lipid regulating agent dissolved in at least one structured lipid. The present Example 2 illustrates the compositions of the present invention.

Applicants submit that since Lacy *et al.* fail to disclose or suggest even the basic elements of independent claim 1 (from which claims 2-8, 12-17 and 19 depend) as argued above, the cited reference also fails to suggest the more specific requirements of the dependent claims. Therefore Applicants respectfully request withdrawal of the Sec. 102(b) rejection.

#### Discussion of the 35 U.S.C. Sec. 103(a) Rejection

Claims 1-20 have been rejected under 35 U.S.C. Sec. 103(a) as being unpatentable over Lacy *et al.*, U.S. Patent No. 5,645,856. Specifically, the Office Action stated that it would be within the skill of the art to use any lipid-regulating agent, and to select a proper triglyceride with the expectation of obtaining the results of Lacy *et al.* As the Applicants have explained above, Lacy *et al.* do not disclose their compositions, and in fact teach away from them. Applicants herewith incorporate their arguments made above with respect to this reference.

Applicants do not believe that the cited reference teaches or suggests their invention as set forth in claim 1. Moreover, since Lacy *et al.* fail to disclose or suggest even the basic elements of independent claim 1 (from which claims 2-8, 12-17, 19 and 20 depend) as argued above, the cited reference also fails to suggest the more specific requirements of the dependent claims. Therefore Applicants respectfully request withdrawal of the Sec. 103(a) rejection.

urged that the subject application, as amended, is in condition for allowance. If any fees are incurred as a result of the filing of this paper, authorization is given to charge Deposit Account Number 04-1644.

Respectfully submitted,

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**CERTIFICATE OF EXPRESS MAILING**

I hereby certify that this Preliminary Amendment and any other documents referred to as enclosed herein, are being deposited in an envelope with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated below and addressed to Commissioner for Patents, Washington, D.C. 20231.

EL733166917US

*Express Mail Label No.*

02/16/01

*Date of Deposit*

Carla Phillips

*Typed/Printed Name of Person Mailing Correspondence*

Carla Phillips

*Signature of Person Mailing Correspondence*

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